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09/881,041	06/15/2001	Glenn Philander Vonk	P-5013	5157

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EXAMINER
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SEREBOFF, NEAL

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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11/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/881,041	<b>Applicant(s)</b> VONK ET AL.	
	<b>Examiner</b> NEAL R. SEREBOFF	<b>Art Unit</b> 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Amendment***

1. In the amendment dated 9/25/2009, the following has occurred: Claim 1 has been amended; Claims 8 - 25 have been canceled. Claims 1 - 7 are pending.

***Notice to Applicant***

2. The Information Disclosure Statement (PTO-1449) submitted on 10/5/2009 has been considered.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 – 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 includes the limitation, “and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle.” The Examiner cannot find explicit, implicit or inherent support for this limitation. Claims 2 - 7 are rejected as they depend upon claim 1.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 – 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 includes, “advise the patient on how to improve the integration.”

- It is not clear from the claim exactly what the scope of the advice includes; integration improvements are subjective.
- It is further not clear who or what advises the patient. The Examiner understands that the advice is performed by the health care provider.
- The Examiner therefore understands the limitation to be non-functional descriptive information with no patentable weight. Claims 2 – 7 are rejected for the same reasons as they depend upon claim 1.

***Claim Rejections - 35 USC § 103***

8. ***Claims 1 – 7 are*** rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al. (5,867,821 ; hereinafter Ballantyne), in view of Joao (6,283,761 ; hereinafter Joao), and in view of Summerell et al. (5,937,387; hereinafter Summerell).

9. As per currently amended Claim 1, Ballantyne discloses a system for monitoring health-related conditions of patients, comprising:

- (1) a plurality of remote monitoring stations, each being configured to receive patient health-related data pertaining to a respective patient (Ballantyne: col. 2, lines 25-26; Fig. 1-3); and
- (2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and

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outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (Ballantyne: abstract; col. 1, line 65 - col. 2, line 63; col. 15, lines 56-65; Fig. 1-12 B).

Ballantyne, however, fails to expressly disclose a system for monitoring health-related conditions of patients, comprising:

(2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on

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said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions

(3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools; and

(4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information, which relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle, needs to be conveyed to the patient in response to said progress determination.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Summerell. In particular, Joao and Summerell disclose a system for monitoring health-related conditions of patients, comprising:

(2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database (Joao: 20: 13 – 19 and 25: 13 – 19),

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said computer network configured (Joao: 25: 11 - 14) to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (Joao: 25:34 – 47)

(3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30); and

(4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information, which relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle, needs to be conveyed to the patient in response to said progress determination (Joao: abstract; col. 4, line 26-col. 5, line 54; col. 41, line 56-col. 43, line 29; Fig. 1-15B).

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One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne and Summerell with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

10. As per currently amended claim 2, Ballantyne discloses a system as claimed in claim 1, wherein:

(1) each of said remote monitoring stations comprises at least one measuring device, configured to measure a physiological condition of said respective patient, and to provide data representative of said physiological condition for inclusion among said patient health-related data (Ballantyne: col. 11, lines 18-27).

Ballantyne, however, fails to expressly disclose a system as claimed in claim 1, wherein:

(2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.



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Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein

(2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

11. As per currently amended claim 3, Ballantyne discloses a system as claimed in claim 1, wherein:

said remote monitoring stations are configured to provide said patient health-related data to said computer network over the Internet (Ballantyne: Fig. 1, 5, 7B)

12. As per previously presented claim 4, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein:

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(1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30) (Examiner has noted insofar as claim 4 recites "selected from the group consisting of Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific disease state monitoring, depression scales, nutrition assessment tools, quality of life assessment tools," quality of life assessment tools is recited.).

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein:

(1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

13. As per currently amended claim 5, Ballantyne discloses a system as claimed in claim 1, wherein:

said computer network is configured to generate reports, each including health-related information pertaining to a respective said patient (Ballantyne: col. 15, lines 22-67; col. 16, lines 1-13).

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14. As per currently amended claim 6, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.

Nevertheless, these features are old and well known in the art, as evidenced by Joao. In particular, Joao discloses a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database (Joao: col. 4, lines 31-47; col. 37, lines 35-47; Fig. 1).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Joao within the Ballantyne system with the motivation of facilitating the creation, management, quality, efficiency and effectiveness of healthcare services (Joao: col. 2, lines 38-54).

15. As per currently amended claim 7, Ballantyne discloses a system as claimed in claim 1, wherein:

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each said remote monitoring station receives from its respective said patient said patient health- related data including data pertaining to the cardiovascular system of said patient (Ballantyne: col. 11, lines 18-27).

### ***Response to Arguments***

16. Applicant's arguments filed 9/25/2009 have been fully considered but they are not persuasive.

17. Rejections under 35 U.S.C. 103(a)

- The Applicant states, “Applicant’s respectfully submit that the payer described in FF16 (Joao 28:38 – 60) were arguably assumed to be a patient, this assumption appears to be in contradistinction with the reset of Joao that specifically defines “patient” and “payer” as different entities (see, for example the different definitions provided for “patient” and “payer” in Joao at 12:51-57 and at 13:8-19, respectively, and the separate listings of patients and payers in Joao such as at 2:22, 2:58 and 4:11-25.
  - The Examiner notes that it is not clear from the claim whether the information is directed to the patient or the health provider. Therefore, the Applicant’s arguments only potentially applicable if the claims are read through the Applicant’s narrow review.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./

Examiner, Art Unit 3626

10/20/2009

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626